MAR 1 3 2014

5. 510(K) SUMMARY

Table 5-1 Summary Table

Submitter:	Emerge Medical
Submitter's Name:	Michelle Potvin, Vice President of Quality Assurance michelle.potvin@emergemedical.com
Submitter's Address:	720 S. Colorado Blvd. Suite 550-S Denver, CO 80246
Submitter's Telephone:	720.459.6392
Submitter's Fax:	(800) 698.1440
Contact Person:	Meredith L. May, MS, RAC 719.337.7579 MMay@EmpiricalTesting.com
Date Summary was Prepared:	15 January 2014
Trade or Proprietary Name:	Emerge Medical Distal Radius Set
Common or Usual Name:	Single/multiple component metallic bone fixation appliances and accessories (§888.3030)
Classification:	Class II per 21 CFR §888.3030
Product Code:	HRS
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Emerge Medical Distal Radius Set will include 6 and 9 locking hole head variations with pairs of locking and non-locking holes in the shafts to be used with a variety and screws to be FDA cleared and offered as a system of implants to be used for internal bone alignment and fixation of fractures of the radius. The system features plates with six and nine hole head variations with three and five hole shafts, bone screws for fixation, and a set of instruments to facilitate installation and removal of the implants. The plates have screw holes, which allow for attachment to the bones or bone fragments. The plates are fabricated from medical grade stainless steel (ASTM F139-12).

TECHNOLOGICAL CHARACTERISTICS

The Emerge Medical Distal Radius Set has the same or similar design, sizes, indications for use, and materials as the predicate systems. The sizes differ slightly, but present no new risks.

INDICATIONS FOR USE

The Emerge Medical Distal Radius Set is intended for fixation of complex intra-articular and extra-articular fractures and osteotomies of the distal radius and other small bones.

The Emerge Medical Distal Radius Set is not intended for use with active or latent infection, osteoporosis, insufficient quantity or quality of bone/soft tissue, material sensitivity (if suspected tests should be performed prior to implantation), sepsis, patients who are unwilling or incapable

of following postoperative care instructions. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

The indication for use for the Emerge Medical Distal Radius Set is similar to that of the predicate devices listed in Table 5-2.

Table 5-2 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**
K091644	2.4mm LCP Volar Column Distal Radius Plates	Synthes
K012114	Locking Distal Radius Plating System	Synthes

PERFORMANCE DATA

Static and Dynamic Bending of the Emerge Medical Distal Radius Set were evaluated via finite element analysis (FEA) demonstrating the predicate device was the worst case scenario. The results of this non-clinical testing show that the strength of the Emerge Medical Distal Radius Set is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Emerge Medical Distal Radius Set is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2014

Emerge Medical, Inc.
% Ms. Meredith May MS, RAC
Senior Manager
Empirical Consulting
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K140107
Trade/Device Name: Emerge Medical Distal Radius Set
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: January 15, 2014
Received: January 15, 2014

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: December 31, 2013 *See PRA Statement on last page.*

510(k) Number *(if known)* K140107

Device Name
Emerge Medical Distal Radius Set

Indications for Use (*Describe*)

The Emerge Medical Distal Radius Set is intended for fixation of complex intra-articular and extra-articular fractures and osteotomies of the distal radius and other small bones.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L. Frank -S

Division of Orthopedic Devices

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